

**Essay #1:**

Describe your specific area(s) of expertise, the problem area(s) where you apply your expertise, and the people and organizations who seek your scientific knowledge, judgement and ability to help make decisions and solve environmental problems. Discuss the scope of problems you address and your approach to addressing those problems. Include examples of how you interact with officials, managers, other professional experts, and the public. At the GS-14 level, the candidate should be a nationally recognized scientific expert with demonstrated experience in providing valued guidance to resolve difficult, novel or obscure scientific problems affecting Agency programs. Note that Question 1 is oriented toward the position in which you serve, the nature of the job itself, the expectations and demands, and your approach to them.

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My specific areas of expertise are risk assessment, environmental epidemiology, and the application of systematic review methods to chemical assessments. I have applied these areas of expertise to a variety of products developed by the Environmental Protection Agency (EPA), including assessments for the [ HYPERLINK "<https://www.epa.gov/iris>" ] (IRIS), [ HYPERLINK "<https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments>" ] (PPRTVs), [ HYPERLINK "<https://www.epa.gov/chemicals-under-tsca>" ] (TSCA) in the Office of Pollution Prevention and Toxics (OPPT), and other targeted analyses. These assessments are foundational to support the decision-making needs of the EPA Program Offices, other federal or state agencies, and international bodies.

**Risk Assessment**

For over 25 years the focus of my career has been the evaluation of human health as it relates to exposure to environmental chemicals. The following highlights my experience in 3 specific areas of risk assessment: (1) site risk assessment, (2) IRIS toxicity evaluations, and (3) PPRTV assessments. These activities demonstrate my role and interactions with the community of stakeholders in addressing risk assessment issues.

**1. Site Risk Assessment**

- From 1989-1991, as a Project Toxicologist in environmental consulting, I provided epidemiological, statistical, environmental health management, and quality assurance/quality control (QA/QC) expertise for site investigations related to exposures to hazardous waste, toxic substances, groundwater and air pollutants.
- After receiving my doctorate in Environmental Epidemiology, I joined the EPA to work as a Regional Superfund Risk Assessor (1997-2000). In this capacity I developed human health risk estimates using site specific exposure information and chemical-specific toxicity information. The risk estimates were used by Superfund Remedial Project Managers (RPMs) in their remedial action plans and by On Scene Coordinators (OSCs) in their removal action plans to make informed decisions regarding effective and safe clean-up of contaminated sites. I also provided technical expertise and advice with respect to mobility, fate and transport, volatility, and flammability of chemicals found at sites to support clean-up efforts.
- As the Regional Science Liaison (RSL) for Region 2 (2000-2002) I provided critical support during the regional EPA's World Trade Center Disaster Response in 2001. Specifically, in coordination with other Federal and state agencies, I prepared summaries and daily briefings

for the EPA and other governmental managers and scientists on contaminant levels and potential public health impacts related to the World Trade Center disaster. I also assembled communication releases such as poster presentations and fact sheets for government officials, scientists and non-technical public audiences. I received a Superior Accomplishment Recognition Award for this work.

- As a risk assessor at the National Homeland Security Research Center (NHSRC) from 2002 to 2004 I provided risk assessment support for the development of multiple, various and complex human health risk assessments involving threat scenarios, exposure to agents released in buildings and for emergency response actions for chemical releases at fixed facilities.

## **2. IRIS Chemical Assessments**

- From 2004 to the present I have worked as a Chemical Manager for the IRIS Program.<sup>1</sup> As a Chemical Manager, I led the development of several IRIS assessments products, including dichlorobenzenes (3 isomers), [ [HYPERLINK "https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0418tr.pdf"](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0418tr.pdf) ], [ [HYPERLINK "https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0422tr.pdf"](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0422tr.pdf) ], and chloroform (inhalation). Duties of a Chemical Manager include leading a team of experts contributing to the assessments, project management, integrating toxicological and epidemiological evidence to prepare draft hazard conclusions, coordinating with statisticians who conduct dose-response analysis, resolving scientific issues, and providing technical direction to any contract support used during the development of the assessment. Additionally, the Chemical Manager remains the key technical contact for the assessment, facilitating technical and scientific support to risk managers. This expertise is also extended to support other federal and state agencies that use these assessments.
- As a Contracting Officer's Representative (COR) I provide oversight and technical direction to contractors working on IRIS-related tasks. Initial COR certification involved 8 hours of in-person instruction and an additional 32 hours of on-line training. Recertification as a COR requires accumulation of at least 40 hours of Continuous Learning Points (CLPs) every 2 years. My certification is current and has been in effect for the duration of my IRIS Chemical Manager tenure.

## **3. PPRTVs Assessments**

- From 2004 to 2016 I served as a standing member of the PPRTV review committee and contributed to the development of more than 40 PPRTV assessments (see CV Appendices). PPRTVs, which typically address data poor chemicals, are provisional values developed in response to requests from the EPA's Office of Land and Emergency Management (OLEM; aka Superfund) to the Superfund Health Risk Technical Support Center (STSC) within the EPA's ORD.

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<sup>1</sup> The IRIS Program refers to a group of scientists within EPA's Office of Research & Development (ORD) who produce IRIS assessments and provide expert scientific support to the EPA regulatory programs and their regional offices. This expertise is also extended to support other federal and state agencies that use these assessments.

## **Environmental Epidemiology**

Determining how environmental exposures impact human health and how non-genetic risk factors influence disease processes fascinated me early on in my career, leading me to pursue a doctoral degree in Environmental Epidemiology from Columbia University (Dr.PH was granted in 1997). My experience as an environmental epidemiology expert at the EPA includes the following:

- As an epidemiologist in the IRIS Program I regularly review and evaluate epidemiology studies as part of hazard identification and dose response analyses in assessment products and publications. Recent examples include ammonia (inhalation), phthalates, acrolein, chloroform, and naphthalene.
- As co-chair of the IRIS Epidemiology Workgroup from 2013 to 2017 I worked with outside technical experts to develop (and test) outcome specific study evaluation protocols that summarize the criteria used to evaluate the internal validity of studies.
- Since 2018, I have provided significant epidemiology and systematic review support for TSCA to meet urgent statutory deadlines for the first 10 TSCA risk evaluations released since passage of the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, which updates the Toxic Substances Control Act. For this work I received an ORD 'Exceptional Technical Assistance to the Regions or Program Offices' Award for collaborative leadership and support to OPPT. My expertise was particularly applicable to the following TSCA chemicals: hexabromocyclododecane (HBCD), perchloroethylene (Perc), carbon tetrachloride (CCl<sub>4</sub>), trichloroethylene (TCE), and methylene chloride (DCM or dichloromethane).
- I utilized my epidemiological expertise in systematic review harmonization collaborations with staff at the Agency for Toxic Substances and Disease Registry (ATSDR), Texas Commission on Environmental Quality (TCEQ) and the Department of Environmental Science and Analytical Chemistry (ACES) at Stockholm University (see essay 4).

## **Systematic Review**

My third area of expertise is the use of the systematic review to enhance the transparency and increase the scientific rigor of chemical assessments. Systematic review helps scientists retrieve, organize, evaluate, synthesize, integrate and present scientific information in a structured and transparent manner thus reducing bias in the assessment. Since 2011, the IRIS Program has been

under pressure to implement systematic review (NRC, 2011<sup>2</sup>; NRC, 2014<sup>3</sup>). Only recently has the IRIS Program fully incorporated the principles of systematic review in its assessments, with substantial progress made since 2017 (NAS, 2018)<sup>4</sup>. A 2019 U.S. Government Accountability Office (GAO) report acknowledged the progress the IRIS Program has made to produce timely, transparent, and credible assessments in support of the EPA's mission. I have been on the front line of implementing the new systematic review methods into IRIS assessments or assessment-related publications. For this reason, I am often asked to provide systematic review support to OPPT and training for ORD staff and student interns. Specific activities include:

- Developing a new systematic evidence map assessment product as an innovative application of systematic review methods. Systematic evidence maps (SEMs; also referred to as systematic maps or evidence maps) are gaining visibility in environmental health for their utility to inform decision-making and risk management priority setting and to serve as problem formulation tools to refine the focus of questions that get addressed in full systematic reviews. SEMs do not seek to draw assessment conclusions, but instead assemble and catalogue evidence, utilizing systematic search and selection strategies to produce searchable databases of studies along with detailed descriptive information that can be used to inform risk management considerations. Acrolein and naphthalene journal submissions are examples of SEMs to which I contributed.
- Developing standard operating procedures (SOPs) that reflect efficient and pragmatic application of a systematic review process that can be deployed in IRIS, PPRTV and OPPT assessments.<sup>5</sup>
- Providing training in cutting-edge systematic review software (Swift Active, DistillerSR, HAWC) and methods used for study evaluation, data extraction and QC to cross-EPA assessment teams, EPA student interns and for external partners in federal and state agencies (ATSDR, TCEQ) and academia (ACES at Stockholm University)
- Applying systematic review methods to the IRIS chloroform, ammonia (oral) and uranium assessments, and SEMs for phthalates, acrolein, and naphthalene

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<sup>2</sup> National Research Council. 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press. [ HYPERLINK "<https://doi.org/10.17226/13142>" ]

<sup>3</sup> National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press. [ HYPERLINK "<https://doi.org/10.17226/18764>" ].

<sup>4</sup> National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. [ HYPERLINK "<https://doi.org/10.17226/25086>" ].

<sup>5</sup> The SOPs focus on workflows for screening studies for relevance, summarizing study design and results from included studies ("data extraction"), study evaluation, and visualizations using interactive web-based software such as Tableau or Health Assessment Workspace Collaborative (HAWC).

## Essay #2:

**What degree of independence and level of supervision do you receive when providing scientific advice or developing science products, and how is your progress typically reviewed?** GS-14 candidates should explain how their work products are normally accepted without significant change and provide examples that demonstrate how these products and their scientific expertise are considered technically authoritative.

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I have more than 2 decades of experience in risk assessment, including more than 15 years conducting Integrated Risk Information System (IRIS) assessments. At this point in my career, I have achieved a high degree of independence. Some work products and activities that demonstrate this independence are highlighted below. All the risk assessment products are considered technically authoritative and are used in decision making by the Environmental Protection Agency (EPA) and others.

### **Risk Assessment**

#### *Chemical Manager for the IRIS Program*

I served as a Chemical Manager in the IRIS Program and led the development of several assessment products, including dichlorobenzenes (3 isomers), [ [HYPERLINK "https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0418tr.pdf"](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0418tr.pdf) ], [ [HYPERLINK "https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0422tr.pdf"](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0422tr.pdf) ], and chloroform (inhalation) (see essay 1). I oversaw all aspects of the chemical assessments and document preparation independently and with little technical supervision. This included reviewing, evaluating, interpreting and synthesizing toxicological and epidemiological data, developing evidence tables, identifying and resolving science issues, understanding potential policy issues, briefing team members, supervisors, management, and other scientists on scientific issues and responding to comments from internal and external reviewers. Assessment progress and team member participation were reviewed and tracked by program management tools. Scientific content was evaluated through a rigorous review process involving agency and interagency reviews and external independent peer review. IRIS products are considered technically authoritative by many national and international bodies because of the many levels of internal and external peer review they undergo.

#### *Provisional Peer Reviewed Toxicity Values (PPRTVs)*

As a member of the PPRTV committee from 2004 to 2016 I reviewed preliminary drafts, discussed and resolved scientific issues with other reviewers and assisted in the determination of critical effects and critical studies for use in developing more than 40 PPRTVs (see CV Appendices). PPRTVs are used by the Office of Land and Emergency Management (OLEM; aka Superfund) as Tier 2 assessment products when an IRIS assessment is not available. My membership on this committee demonstrates that others within the EPA consider the scientific expertise I provide as technically authoritative. While the committee is by design a team, my individual scientific opinions were developed independently.

#### *Risk Assessment Forum (RAF)* (see essay 3 & 4)

As a member of several RAF Technical Panels and Writing Teams I provided risk assessment expertise independently for the following:

- Cumulative Risk Assessment (CRA) research planning activities (as Chair of the Subcommittee on Research Planning)
- CRA workshop development and implementation (as Chair)
- Development of the current CRA draft guidance on Planning and Problem Formulation (as a Writing Team member)
- Development of 2 White Papers (as a member of the Probabilistic Risk Assessment (PRA) Technical Panel): [ HYPERLINK "<https://www.epa.gov/sites/production/files/2014-11/documents/raf-pra-faq-final.pdf>" ]<sup>6</sup> and [ HYPERLINK "<https://www.epa.gov/sites/production/files/2014-12/documents/raf-pra-white-paper-final.pdf>" ]<sup>7</sup> (files: ScientificContribution# AGalizia; ScientificContribution# AGalizia)
- Development (as co-author) of the [ HYPERLINK "<https://www.epa.gov/sites/production/files/2015-01/documents/ddef-final.pdf>" ]<sup>8</sup> (file: ScientificContribution# AGalizia)

These work products are considered technically authoritative because of the many internal levels of review. My inclusion on several RAF Technical Panels and EPA initiatives (see CV) confirms that others within the EPA consider the risk assessment expertise that I provide as technically authoritative. My contributions to these RAF discussions and writing products were completed independently.

### **Support for the IRIS Program and for the Office of Pollution Prevention and Toxics (OPPT)**

Currently I support the IRIS Program, PPRTVs, OPPT and external partners by serving as a key technical contact in the implementation of systematic review activities, both general systematic review methods and those targeted towards my epidemiologic expertise. The range of this support is described below.

#### **Implementation of Systematic Review**

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<sup>1</sup> U.S. EPA, Office of the Science Advisor, Risk Assessment Forum. White Paper: Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions. (2014). EPA/100/R-09/001B. Washington, D.C.: Risk Assessment Forum, Office of the Science Advisor, USEPA.

[ HYPERLINK "<https://www.epa.gov/sites/production/files/2014-11/documents/raf-pra-faq-final.pdf>" ]

<sup>2</sup> U.S. EPA, Office of the Science Advisor, Risk Assessment Forum. White Paper: Probabilistic Risk Assessment Methods and Case Studies. (2014). EPA/100/R-14/004 [ HYPERLINK

"<https://www.epa.gov/sites/production/files/2014-12/documents/raf-pra-white-paper-final.pdf>" ]

<sup>3</sup> [ HYPERLINK "<https://www.epa.gov/sites/production/files/2015-01/documents/ddef-final.pdf>" ]

The development of high-quality chemical assessment products requires coordinated efforts across multidisciplinary teams and is facilitated by well-defined standard operating procedures (SOPs) and templates to foster consistency across various assessment products (e.g., IRIS, PPRTVs, systematic evidence maps). All assessment products produced within my Division are now developed using systematic review methodology to increase transparency and reduce potential bias. Specialized software applications, including use of artificial intelligence, are used to make the workflows consistent and efficient. I was one of the early implementers of systematic review within my Division and have established myself as a key technical authority on both systematic review principles, implementation and specific application to epidemiological evidence. Examples of my technical authority include:

- I was instrumental in the implementation of the IRIS Handbook (which provides SOPs for producing IRIS assessments using systematic review methods). I was one of the first in my Division to apply the Handbook methods to assessment products, including chloroform and uranium. After establishing familiarity with the methods, I began training others within and outside of my Division, including external parties. Training included online training, targeted consultation, and development of detailed standard operating procedure materials (e.g., videos and step by step instructions for software). Some examples of this training include:
  - For IRIS and PPRTV staff, I provided systematic review training on screening for relevance (title and abstract and full text) in DistillerSR software or the machine-learning application SWIFT Active; on study evaluation using Health Assessment Workspace Collaborative (HAWC) software; and on data extraction in HAWC for epidemiology evidence.
  - For OPPT I provided training in new systematic review software (SWIFT Active, DistillerSR, HAWC) and in methods used for study evaluation and data extraction, incorporating quality control into the process. In addition to training I provided significant epidemiological systematic review support to OPPT in 2018 and 2019 to help meet their assessment deadlines. I was awarded cash and time off awards for this support.
  - For external partners (Agency for Toxic Substances and Disease Registry (ATSDR), Texas Commission on Environmental Quality (TCEQ) and the Department of Environmental Science and Analytical Chemistry (ACES) at Stockholm University) I provided systematic review training on methods used for study evaluation, data extraction and quality control through establishing collaborative pilot assessment projects: ATSDR – carbon disulfide, TCEQ – cumene, ACES – triphenyl phosphate. These pilot collaborations are ongoing, with cumene anticipated to be completed by summer 2020.
- I provided systematic review expertise for evidence mapping. Evidence maps are pre-decisional analyses assembled using systematic review software. They do not present hazard or dose-response information but do inventory the available evidence to help determine whether new evidence is likely to result in a change to an existing health reference value, to inform decision-making and risk management priority setting, to identify key research gaps, and to serve as a problem formulation tool to refine the focus of questions that get addressed in full systematic reviews.

These systematic review tasks have been performed independently with minimum supervision. Training documents (SOPs and presentations) and form development for data extraction can be regarded as authoritative because these documents were refined based on broad feedback and are now regularly used by assessment staff within and outside of EPA.

### Epidemiology Support

Providing scientific expert advice in epidemiology for the IRIS Program and OPPT includes the following:

- As the co-chair of the Epidemiology Workgroup in the IRIS program I provided leadership and expertise for the development and testing of study evaluation protocols for epidemiology studies by:
  - Leading the development of phthalate-related protocols for asthma, pulmonary function, semen parameters, male reproductive hormones, diabetes, immune and thyroid with outreach to outcome-specific experts for their needed input and review. External expert review ensures the protocols are technically sound and authoritative. These protocols are being used by staff to assist in the development of assessment products and continue to be refined based on staff's experience.
  - Developing criteria used to evaluate confounders in epidemiology studies and more generally developing criteria for core epidemiology questions, prompting questions and follow up questions that would apply to most exposures and outcomes. These criteria are being used by staff in their study evaluation and are evolving with use. As such they are considered technically authoritative.
- As an epidemiologist in the IRIS Program I provide ongoing independent epidemiological support and expertise that requires minimal supervision, by:
  - Assisting in the design and implementation of a systematic review process that includes a comprehensive literature search and screening strategies for epidemiology studies
  - Evaluating epidemiological studies for study quality and hazard identification for IRIS assessments
  - Providing epidemiology and systematic review support for OPPT to meet the requirements associated with [ [HYPERLINK "https://www.epa.gov/chemicals-under-tsca"](https://www.epa.gov/chemicals-under-tsca) ] (TSCA) chemical risk evaluation

My epidemiology support requires minimal supervision and is completed independently.



### Essay #3:

**To what extent is originality required to perform your work assignments?** Describe the availability of existing practice and guidance in your area of work, and where your work has resulted in modifications to guidelines/guidance or the creation of new guidelines/guidance. GS-14 candidates should provide examples of how they used good judgement, versatility, ingenuity, and innovation to apply their expertise in situations where guidelines or methods were not clear or did not exist.

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Scientific evaluation requires considerable expert judgement, in many cases extending beyond my epidemiological expertise. Each assessment has its unique set of challenges requiring versatility and good judgement to resolve. With respect to innovation, my work in systematic review was instrumental in informing and advancing methodology where guidelines were incomplete or lacking in the Integrated Risk Information System (IRIS) Program. This includes application of systematic review methods in the consideration of epidemiological evidence as well as establishing efficient workflows using specialized software applications to screen, evaluate and summarize studies. In addition, my Risk Assessment Forum (RAF) work has been a venue for using expert judgment and innovation to advance risk assessment practice across the Environmental Protection Agency (EPA). The following section summarizes specific examples of how I applied good judgement, ingenuity and innovation when information or guidelines were lacking.

### Systematic Review

- Used innovation to develop consistent standard operating procedures (SOPs) and workflows for use by IRIS and the Office of Pollution Prevention and Toxics (OPPT) through collaborative efforts to modify Populations, Exposures, Comparisons, and Outcomes (PECOs), screening strategies, literature inventories and study evaluations. Having consistent SOPs developed through collaboration has had significant impact on fostering consistency in the application of systematic review across different assessment programs.
- Displayed originality and ingenuity by using my work on the chloroform assessment as a pilot to engage EPA partners in the utility and versatility of systematic evidence maps (SEMs) as products that can inform future directions of assessments. This pilot was subsequently incorporated into our assessment workflows and became instrumental in prioritization and resource allocation. In addition, SEMs were adopted into our assessment workflows for phthalates, acrolein, and naphthalene.
- Worked to continuously enhance pragmatic and practical applications of systematic review to EPA workflows by identifying, innovating, and adapting best practices and by applying iterative detailed strategies for study evaluation and data extraction which resulted in improved evaluations
- Organized pilots for testing PECO, screening strategies, literature inventories and study evaluations and modified elements as needed for better efficiency
- Provided systematic review support for OPPT to help them meet regulatory requirements associated with [ HYPERLINK "<https://www.epa.gov/chemicals-under-tsca>" ] (TSCA)

chemical risk evaluation, a high priority for the Agency requiring a rapid turnaround by using creativity and innovation to meet tight deadlines (EPA award received)

### **Epidemiology Support**

- Developed and tested various outcome-specific study evaluation protocols for several outcomes (see CV) where guidelines for establishing such criteria did not exist. This entailed working with outside experts, applying expert judgment to develop draft criteria, and refining the criteria based on discussions with peers. Once developed and used in assessment products these protocols then become available to the public.
- Used expert judgement, flexibility and innovation in applying epidemiology expertise to support a quick turnaround for OPPT regulatory requirements by suggesting changes to criteria and to data extraction forms used in evaluation of epidemiology studies (EPA award received)

### **Risk Assessment**

- Developed exposure evaluations that required expert judgements about unique exposure circumstances at a wide variety of contaminated site investigations for use by site managers and risk managers by gathering and using site-specific and activity-specific information
- Participated in the resolution of scientific issues related to the choice of critical study, hazard identification, data modeling and uncertainty factors for at least 40 [ HYPERLINK "<https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments>" ] (PPRTVs) (see CV Appendices) by using expertise and scientific judgement

### **Risk Assessment Forum (RAF)**

- As a member of the RAF Cumulative Risk Assessment (CRA) Technical Panel I chaired the Subcommittee on Research Planning for CRA from 2004 to 2009 and was responsible for identifying needs, issues and priorities of the Regions and Program offices as they relate to CRA and for providing direction, priorities and perspective to CRA Research Planning where none existed before.
- As a member of the RAF CRA Writing Team, I assisted in the development of the current draft CRA Guidance titled 'Guidance for Cumulative Risk Assessment; Planning and Problem Formulation, (revised Risk Assessment Forum Review Draft, 2019)' (see essay 2). This describes steps for the planning and problem formulation of CRAs and offers guidance for when such assessments might be appropriate. It updates and supersedes the 1997 [ HYPERLINK "[http://www.epa.gov/sites/production/files/2015-01/documents/cumrisk2\\_0.pdf](http://www.epa.gov/sites/production/files/2015-01/documents/cumrisk2_0.pdf)" \h ]. This guidance places emphasis on providing a uniform yet flexible CRA planning and problem formulation methodology to be used as a decision support tool for risk management at the Agency, thus advancing risk assessment through innovation.

- As a member of the Probabilistic Risk Analysis (PRA) Technical Panel I advanced the field of risk assessment and helped to inform decision making at the Agency, by contributing to innovative efforts put forth in two white papers on guidance for PRA (see essay 2).
- Authored, with other Agency scientists, the ‘Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Inter-Species and Intra-Species Extrapolation’ where none existed (see essay 2). This guidance describes an innovative approach for identifying and using pertinent information for developing data-derived extrapolation factors (DDEFs) for the purposes of developing Reference Doses (RfDs), Reference Concentrations (RfCs), or related metrics (such as hazard index, margin of exposure) in lieu of using default values and processes thereby reducing uncertainty in RfD and RfC values, thus advancing risk assessment.

#### Essay #4:

**What impact have your contributions made with regard to making a positive difference in Agency decisions, influencing the direction of environmental programs and policies, defining new critical issues, and advancing your scientific area of expertise?** Describe how your work products (including peer-reviewed journal articles, assessments, technical reports, models, tools, policy and guidance documents or briefings) have influenced Agency actions or advanced a particular area of science. Discuss your personal role in both serving on and leading teams, and how your efforts contributed to the broad goals and objectives of the team. List any recognition or awards received for these contributions. GS-14 candidates should be recognized throughout the Agency and professional societies as a technical expert serving on scientific committees and providing credible advice and support for other professionals and staff engaged in field or regional operations. The candidate should provide details on the impact of their work on major programs in the Agency or the direction of and state of the science in their area of expertise. Note that this question is oriented to allow the candidate to showcase their accomplishments, describing the most significant things they have done and what impact it had on the Agency and the national and international scientific community.

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Assessments are considered influential products in the Environmental Protection Agency (EPA) because they are inherently designed to inform significant statutory decisions across the EPA and among EPA partners and stakeholders. My career at the EPA, starting as a toxicologist in EPA's Region 2 through my involvement in a diverse portfolio of assessments including [ [HYPERLINK "https://www.epa.gov/iris"](https://www.epa.gov/iris) ] (IRIS), [ [HYPERLINK "https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments"](https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments) ] (PPRTVs), [ [HYPERLINK "https://www.epa.gov/chemicals-under-tsca"](https://www.epa.gov/chemicals-under-tsca) ] (TSCA), has been devoted to producing assessment products and providing scientific and expert advice to inform decisions. My contributions (journal articles, a portfolio of assessment products, technical reports, guidance documents and presentations) have influenced Agency actions or advanced science in the following ways.

#### **Assessment Products**

- Providing hazard identification, human health risk estimates, exposure scenario expertise and developing risk-based toxicity values for remedial and removal actions for the Office of Land and Emergency Management (OLEM; aka Superfund) allowed for a quick response for the Regions and Program offices concerning site related risks thus informing site risk decisions which ultimately supported the Agency's mission to protect public health.
- Providing critical support during the regional EPA's World Trade Center Disaster Response in 2001 (see essay 1; award received) by preparing summaries and daily briefings on contaminant levels and potential public health impacts provided the Agency with a means to present data transparently and supported the EPA's mission to protect human health.
- Contributing to the development of national Guidance for Probabilistic Risk Assessment (PRA) (see essay 3) helped advance the Agency's ability to determine, with less uncertainty, human health risks from environmental exposures.

- Authoring several IRIS assessments (as primary technical lead for *dichlorobenzenes*, *dichloroethylene*, and *ammonia (inhalation)*) provided toxicity reference values. IRIS toxicity values are regarded worldwide as an authoritative source of toxicity information (see essay 2) and are used in a variety of decision-making analyses by the EPA and other agencies. For context, due to their complexity and extensive review, the level of effort to complete one complete draft or finalized IRIS Toxicological Review is considered approximately equivalent to 3-5 peer-reviewed manuscripts.
- Providing expertise and scientific judgement in the development of more than 40 PPRTVs (see essay 1 & 2; received awards, 2004, 2006) enabled Programs and Regions to develop timely hazard and risk evaluations.

### **Systematic Review Training and Standard Operating Procedures (SOPs) Development**

- Providing training in cutting-edge systematic review software, study evaluation, data extraction and quality control and in collaborative harmonization methods for conducting systematic review within the EPA (Office of Pollution Prevention and Toxics (OPPT)) and for external partners (Agency for Toxic Substances and Disease Registry (ATSDR), Texas Commission on Environmental Quality (TCEQ) and the Department of Environmental Science and Analytical Chemistry (ACES) at Stockholm University) can potentially reduce duplicative work efforts across assessment programs worldwide.
- Developing SOPs that reflect efficient and pragmatic application of a systematic review process that can be deployed in IRIS, PPRTV, and OPPT assessments (see essay 1) is instrumental in helping to harmonize systematic review methods used across EPA.
- Tailoring an innovative approach (evidence mapping) for rapid systematic review of assessments (see essay 2) can inform decision-making and risk management priority setting.
- Using systematic review tools to screen, perform study evaluation, direct and track data extraction and clean up for over 12 chemicals (phthalates, naphthalene, chloroprene, carbon disulfide, carbon tetrachloride, perchloroethylene, ammonia (oral), PFAS, benzene, mercury salts, ethylbenzene, HBCD, triphenyl phosphate, etc.) and for several assessments I am leading (chloroform, cumene, uranium (planned)) could improve quality, transparency and consistency across assessments and make the process more efficient.

### **Epidemiology Support**

- Developing and testing various outcome-specific study evaluation protocols (see essay 2) advanced epidemiology study evaluation capabilities for IRIS and external partners by providing criteria and rating guidelines for study evaluation where none existed before.
- Providing epidemiology advice for IRIS and OPPT in the evaluation of epidemiology studies aided the development of assessments and evidence maps across the IRIS program and OPPT.
- Providing critically needed epidemiology and systematic review support for OPPT (see essay 1 & 2 ; award received) helped OPPT meet requirements associated with [ [HYPERLINK "https://www.epa.gov/chemicals-under-tsca"](https://www.epa.gov/chemicals-under-tsca) ] (TSCA) chemical risk evaluation, a high priority for the Agency requiring a rapid turnaround.

### **Risk Assessment Forum (RAF)** (see essay 3)

- Chairing the Subcommittee on Research Planning for Cumulative Risk Assessment (CRA) and providing direction, priorities and perspective to Research Planning where none existed before, advanced the field of CRA.
- Developing, organizing and implementing a Workshop in CRA (2014) advanced the field of CRA by engaging Agency decision makers in determining when and why CRA would be useful in decision making.
- Assisting in the development of the current draft CRA Guidance titled ‘Guidance for Cumulative Risk Assessment; Planning and Problem Formulation, (revised Risk Assessment Forum Review Draft, 2019), as a member of the CRA writing team, will advance the field of CRA and provide the Agency with better support tools for risk management.
- Authoring, with other scientists across the Agency, the Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Inter-Species and Intra-Species Extrapolation, enabled the Agency to reduce uncertainties in developing RfDs, RfCs, or related metrics/approaches (e.g., hazard index, margin of exposure) and thus advanced risk assessment.

### **Other Contributions**

- Supporting the development of a workshop with the National Academy of Sciences (NAS) to review advances made to IRIS aided IRIS in providing an opportunity for stakeholder input on the changes to the program, thus continuing EPA’s commitment to improving the IRIS process.
- Developing, along with other colleagues, a poster for ORD’s Board of Scientific Counselors (BOSC) review of the Land research program (2005- 2006) demonstrating that ORD’s research program provided well-defined and scientifically sound products in support of regulatory and policy enabled EPA to gain credibility and public support for national environmental protection efforts of the EPA decisions (Superior Accomplishment Recognition Award received).
- Presenting original data from my doctoral dissertation on respiratory health and on World Trade Center response activities at national meetings advanced the understanding of factors influencing respiratory health (see Bibliography for invited presentations and publications).